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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,230	11/13/2006	Hiroyuki Sato	2006_1547A	7037

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EXAMINER	
MESH, GENNADIY	
ART UNIT	PAPER NUMBER
1796	

NOTIFICATION DATE	DELIVERY MODE
02/04/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/593,230	SATO ET AL.	
	Examiner	Art Unit	
	GENNADIY MESH	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,7 and 8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,7 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1.1. Applicant's amendment filed on October 13, 2009 is acknowledged. Claims 4,6and 9 have been canceled by Applicant. Claims 1, 5, 7 and 8 have been amended. Support for amendment of independent claim 1 has been found in Specification as indicated by Applicant. Other claims amended to correct dependency and minor informalities. Thus, no new matter has been added to the claimed subject matter.

1.2. New Grounds of rejection are introduced due to amendment.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-3, 5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeProspero (US 3,565,869 - reference cited by Applicant) in view of Terado et al (US 6,528,617).

Regarding Claims 1-3, 5 and 8 DeProspero disclosed process for producing polyglycolic acid, substantially free from impurities as residual glycolide and other volatile impurities below 0.2% (see abstract and column2, lines 60 - 63) by subjecting solid ground particles of polyglycolic acid to solid state heat treatment with heated and dried (moisture and oxygen free) inert gas (see Abstract) at temperature from 20 ^{0}C to 190 ^{0}C and reduced pressure- see column 3, lines 14 - 34.

Note that DeProspero at least renders obvious or even meet limitation of claim 1 as "proceeds by solid-phase polymerization to reduce a residual cyclic ester content

down to about 0.3 - 0.8 wt% because, during process disclosed by DeProspero residual cyclic ester content reduced below 0.2 wt%, which is **about** 0.3 wt%, because as it well established in the art, "use of **"about"** is warning that exactitude is not claimed but rather a contemplated variation. When there is no substantial or material difference in the product, and the difference is colorable, merely, there is in fact literal readability, if proper weight is given to the qualifying word **"about"** to amounts **significantly lower or higher than the numerically claimed limitation"**. Kolene Corp. v. Motor City Metal Treating, Inc. (DC EMich) 163 USPQ 214.

DeProspero is silent regarding additional step of heat treatment under **normal pressure**, as it required by amended claim 1, but pointing out, that (see column 3, lines72 - 75) " process is run at subatmospheric pressures, the polymer usually remains at a somewhat lower temperature than that of the gas stream due to the combined effects of the reduced rate of heat transfer and the heat consumed by the impurities in the course of their vaporization. The pressure employed is related to the flow rate used. To use **higher pressures**, higher flow rates are required". Therefore, even DeProspero is silent regarding using normal pressure in additional step, process disclosed by DeProspero can be run at higher pressures.

However, Terado teaches solid phase polymerization of aliphatic polyester with following additional heat treatment step, under flow of gas at normal pressure in order to minimized residual monomer content below 1000 ppm (see column 2, lines 50 - 60 , column 3, lines 35 -65 and Examples).

Therefore, it would be obvious to one of ordinary skill in the art to add additional step of heat treatment at flow of gas at normal pressure per teaching of Terado in order to decrease residual cyclic ester in process disclosed by DeProspero.

Regarding limitation of Claim 8 related to particle size - see DeProspero column 4, lines 18 - 33.

3. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeProspero (US 3,565,869) in view of Terado et al (US 6,528,617) as it applied to Claims 1-3,5 and 8 above, combined with Yamane et al.(US 2003/0125431).

As explained above DeProspero in view of Terado discloses process, wherein polyglycolic acid heat treated with inert gas, but is silent regarding adding heat stabilizer to polyglycolic acid.

However, Yamane, teach that (see [0021]) " When the method in which heat history is applied to polyglycolic acid and the method in which the heat stabilizer is added to crystalline polyglycolic acid is used in combination, a polyglycolic acid composition modified in thermal properties and moreover improved in melt stability can be provided".

Therefore, it would be obvious to one of ordinary skill to add heat stabilizer to polyglycolic acid per teaching of Yamane in order to increased thermal stability of the polymer during process of applying heat treatment disclosed by DeProspero in view of Terado.

Response to Arguments

4. Applicant's arguments with respect to claims 1-3, 5, 7 and 8 have been considered but are moot in view of the new ground(s) of rejection.

5. Applicant's arguments related to disclosure of DeProspero and specific benefits of Applicant's invention were found unpersuasive for following reasons:

a) Applicant stated: "... The step of contact with a flowing heated dry gas under normal pressure **is not as effective as application of a reduced pressure** as far as the residual monomer reduction effect is concerned, but is safe and suited for mass production (page 13, lines 17-19). In order to compensate for such a relatively low residual ".

It is noted that Applicant admitted that process claimed by Applicant is not an efficient process as disclosed by DeProspero. It is not clear, why process disclosed by Applicant is more save than process disclosed by DeProspero. It is also noted that the features upon which applicant relies (i.e., **safe process**) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

b) Applicant also stated that: Table 1 on page 25 of the specification, Comparative Example 1 (polymerization temperature: 170 °C) represents solid-phase polymerization, and Comparative Example 4 (polymerization temperature: 230 °C) represents non-solid-phase polymerization (or melt polymerization). Comparing these Examples, it is clear that solid-phase polymerization (residual monomer (glycolide): 0.35 wt.% in

Comparative Example 1) is more advantageous than non- solid-phase polymerization (residual monomer: 1.0 wt.% in Comparative Example 4)".

This argument was found unpersuasive, because DeProspero discloses Solid-phase process at temperatures in a range from 20 ^{0}C to 190 ^{0}C, significantly below 230C and in a range claimed by Applicant.

c) Regarding Applicant's statement that: ... " the residual monomer content below 0.2 wt.% aimed at by the present invention cannot be achieved by only the solid-phase polymerization." note, that DeProspero disclosed that this level, below 0.2 wt% of residual monomer and other volatile impurities is achieved by Solid phase process (see rejection above, paragraph 2 and DeProspero (see abstract and column2, lines 60 - 63).

At least for reasons above Applicant's arguments were found unpersuasive.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GENNADIY MESH whose telephone number is (571)272-2901. The examiner can normally be reached on 10 a.m - 6 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272 1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Milton I. Cano/
Supervisory Patent Examiner, Art Unit 1796

Gennadiy Mesh
Examiner
Art Unit 1796

/GM/